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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/823,119	MULLER, WALTER	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/17/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's IDS filed 07/17/2008 and amendment filed 11/04/2008.

Claims 1-20 are pending and included in the prosecution.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 32-42 of

copending Application No. 10/835,997 in view of US 6,348,501 ('501). The subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are subject matter as follows: transdermal patch comprising self adhesive polysiloxane matrix containing microreservoirs comprising an active agent in an amphiphilic solvent.

However, the present claims are different from the copending claims because the copending claims not claiming capsaicin while the present claims recite capsaicin.

US '501 teaches capsaicin to treat pain administered topically in encapsulated form to reduce the inflammatory effect on capsaicin on the skin (abstract; col.3, lines 13-19; col.4, lines 56-60).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide patch comprising self adhesive polysiloxane matrix containing microreservoirs comprising an active agent in an amphiphilic solvent as claimed by the copending application '997, and deliver capsaicin disclosed by US '501 in the microreservoirs claimed by the copending application because US '501 teaches that encapsulation of topically applied capsaicin reduces its inflammatory effect on the skin, with reasonable expectation of having patch comprising self adhesive polysiloxane matrix containing microreservoirs comprising capsaicin in an amphiphilic solvent to be delivered to the skin without causing any inflammation to the skin at the site of application of the patch.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

3. Applicant's arguments filed 11/04/2008 have been fully considered but they are not persuasive. Applicant argues that while there are certain similarities between the analysis for an obviousness rejection and an obviousness-type double patenting (ODP) rejection, the rejections are not the same, i.e. the analysis for an ODP rejection is limited to a comparison of the respective claims and does not allow for the use of secondary references except for explanatory purposes (e.g. defining the meaning of a claim term). However, in the present case, the '501 patent is being used to address a missing element of the applicants' claim. Therefore, the use of the '501 patent is prima facie evidence that a basis for ODP does not exist.

In response to this argument, it is argued that the present claims 1-20 are obvious over the claims 32-42 currently pending in copending application US ‘997 that has earlier filing date and not reciting any drugs. US ‘501 is used as an explanatory reference showing capsaicin can be administered transdermally. The copending application claims transdermal delivery system having the same structure and composition as the instantly claimed. Therefore, at the time of the invention the structure of the claimed transdermal device was claimed by US ‘977. US ‘501 teaches capsaicin delivered transdermally in encapsulated form to reduce its inflammatory effect

on the skin. Therefore, combination of the claims pending in US '997 that has earlier filing date and the teaching of US '501 would have resulted in the present claims 1-20.

Specification

4. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

5. The objection made to the specification is maintained since applicant did not indicate revision of the specification and has not made any current correction.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-11, 13-15, and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,788,983 ('983) in view of US 6,348,501 ('501), US 6,818,671 ('671) and US 2005/0079206 ('206).

US '983 teaches a transdermal polymer dosage unit comprising backing layer, and adhesive polymer reservoir layer comprising pharmaceuticals in microreservoirs

(abstract; col.7, lines 24-25). The microreservoirs are formed by dissolving/dispersing the pharmaceuticals in the reservoir medium, combining with polymer material, stirring to form the microreservoirs, spreading of the mix onto backing layer and drying at 60 ^{0}C (col.7, lines 26-29; col.9, lines 17-34; col.15, lines 45-50). Suitable solvent or reservoir medium is diols including butanediol (col.8, lines 36-43). The amount of diols in the solvent is at least 20% (col.8, lines 45-48). The adhesive polymer can be silicone adhesive (col.9, lines 23-45). The microreservoirs may contain hydroxypropyl cellulose to provide the desired increased viscosity of the reservoir medium in small amount of between 1-4% (col.9, lines 7-15). Pharmaceuticals suitable to be delivered by this transdermal dosage form include NSAID and vasodilator (col.11, lines 43-55). The pharmaceuticals are present in an amount less than saturation, i.e. less than 100% as required by claim 1 (col.9, lies 1-6). The backing layer is polyester having thickness of 10-200 μm (col.5, lines 47-60).

Although US '983 teaches suitability of the disclosed transdermal system to deliver analgesics and vasodilator drugs, however, the reference does not explicitly teach capsaicin as an active agent dissolved in the microreservoirs.

Although US '983 teaches silicone adhesive suitable for matrix or reservoir having microreservoirs comprising amphiphilic solvent and drug, however, the reference does not explicitly teach mixture of medium tack polysiloxane and high tack polysiloxane.

US '501 teaches capsaicin to treat pain administered topically in encapsulated form to reduce the inflammatory effect on capsaicin on the skin (abstract; col.3, lines 13-19; col.4, lines 56-60). Capsaicin is known to treat neuropathic.

US '671 teaches topical composition to treat topical pain and inflammation including neuralgia comprising wherein the topical composition comprises capsaicin and solvent system comprising 1,3, butylene glycol, dipropylene glycol, and diethylene glycol monoethyl ether (DGME), with DGME is preferred solvent (col.2, lines 16-37, 58; col.3, lines 8-16; col.4, example 3).

US '206 teaches transdermal device comprising microreservoirs containing drug in a self adhesive matrix, wherein the matrix is silicone adhesive made of mixture of high tack polysiloxane (BIO-PSA 4301) and medium tack polysiloxane (BIO-PSA 4201) that is advantageous in providing optimum balance between good adhesion and little cold flux (abstract; paragraphs: 0054-0058).

Therefore, the prior art at the time of the invention recognized encapsulation of therapeutic agent in microreservoirs within silicone reservoir/matrix containing butanediol as disclosed by US '983, and also recognized encapsulation of capsaicin in topical formulation as disclosed by US '501 to avoid skin inflammation. The art further recognized suitability of amphiphilic solvent, to dissolve capsaicin, i.e. butanediol, dipropylene glycol and DGME, with DGME is the preferred solvents for formulation containing capsaicin as disclosed by US '671, and mixture of medium tack and high tack polysiloxane was also known as advantageous for adhesive for transdermal devices at the time of the invention.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal therapeutic system comprising a polymer matrix comprising silicone adhesive and microreservoirs containing therapeutic active agent in butanediol solvent as disclosed by US '983, and deliver capsaicin disclosed by US ‘501 and US ‘671 in the microreservoirs containing amphiphilic solvent disclosed by US ‘983 because US ‘501 teaches that encapsulation of topically applied capsaicin reduces its inflammatory effect on the skin, and further because US ‘671 disclosed that capsaicin is soluble effectively in butanediol and other amphiphilic solvents including DGME, with reasonable expectation of having transdermal device comprising silicone adhesive matrix containing microreservoirs comprising capsaicin in an amphiphilic solvent to be delivered to the skin effectively to treat neuralgia without causing any inflammation to the skin at the site of application of the device. Additionally, it would have been obvious tone having ordinary skill in the art at the time of the invention to deliver transdermal device comprising silicone adhesive matrix containing microreservoirs comprising capsaicin in an amphiphilic solvent as disclosed by the combined teachings of US ‘983, US ‘501 and US ‘671, and replace the silicone adhesive with mixture of high tack polysiloxane and medium tack polysiloxane as taught by US ‘206 because US ‘206 teaches that such a mixture is advantageous in providing optimum balance between good adhesion and little cold flux, with reasonable expectation of having transdermal device comprising microreservoirs comprising capsaicin and amphiphilic solvent and the microreservoirs are dispersed in matrix made

of mixture of high tack polysiloxane and medium tack polysiloxane wherein the matrix has optimum balance between good adhesion and little cold flux.

The references do not teach the coating weight of the drug containing adhesive on the backing layer as claimed by claims 13 and 14. However, such coating weight would have been determined by one having ordinary skill in the art without undue experimentation based on the specific individual use. Therefore, such coating weight does not impart patentability of the claims in absence of superior and unexpected results obtained from this coating weight.

Response to Arguments

8. Applicant's arguments filed 11/04/2008 have been fully considered but they are not persuasive.

> Applicant argues that Chien (US '983) while generally directed towards delivery of active agent is primarily directed to estrogenic compounds and no mention of capsaicin. Applicant agrees that there is no limit on the number of references which can be used to support an obviousness rejection, but argues that the greater the number of references needed is generally an indicia of non- obviousness especially if only selected elements are relied upon in the secondary reference, i.e. an obvious to try rationale is permissible, but only if there is a finite number of identified, predictable solutions which have a reasonable expectation of success. The addition of Holt, Embil and Schacht creates virtually an infinite number of possible solutions when the entire reference of Chien, Holt, Embil and Schacht are considered as a whole.

In response to this argument, it is argued that Chien is directed to generally active agent. Applicant himself admitted this fact. Applicant further admitted that there is no limit to the number of references used to support the rejection. Reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991). Combination of Chien, Holt, Embil and Schacht does

not constitute infinite number of references, and each of the references is relied upon to support the obviousness rejection to show that the elements of the claims were known at the time of the invention. Further, each of the cited references provides motivation to combine its teaching with others. *In re Deuel*, 51 F.3d 1552, 34 USPQ2d 1210 (Fed. Cir. 1995), the Board stated that "when there is motivation to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." In the present case, transdermal delivery of capsaicin that is skin irritating faced those in the art and in order to overcome the problem capsaicin was encapsulated as disclosed by Holt (US '501). Therefore, limited number of solutions was known to avoid skin irritation by encapsulating the irritating substance. Chien provided microreservoirs containing active agent including anti-inflammatory agents. The skilled artisan would have had reason to try the method of encapsulating the irritating capsaicin in microreservoirs with the reasonable expectation that it would be successful. Thus, isolating capsaicin from contacting the skin in the microreservoirs provided by Chien was not an innovation but within ordinary skill and common sense. Embil (US '671) is relied upon to show that capsaicin can be combined with amphiphilic solvent used by Chien to form the microreservoirs, and Schacht (US '206) is relied upon for teaching specific silicone adhesive in the polymer matrix. Additionally, each of the cited secondary references provided motivation to combine with Chien and reasonable

expectation of success drawn from the combination was provided in the rejection as set forth in this office action.

> Applicant argues that Holt's invention is a lotion where the capsaicin is encapsulated by an encapsulation agent. This is neither the mechanism of delivery of the active agent for either the applicants' invention or for Chien. Applicant's invention (topical patch) and Chien's device for transdermal administration are directed toward controlled release of an active agent. Even if it were permissible to combine Holt with Chien, the combined teachings would still lack a teaching of the use of microreservoirs and that the active agents are dissolved therein and that the concentration of capsaicin or a capsaicin analog is at 20 and 90% by weight of the saturation concentration.

In response to this argument, it is argued that Chien teaches the transdermal system comprising microreservoirs as instantly claimed, and further teaches anti-inflammatory drugs and vasodilators, both read on capsaicin. Additionally, Chien teaches amount of the drug less than saturation, i.e. less than 100% which encompasses 20-90% as claimed. Holt desired to reduce skin irritation caused by capsaicin by encapsulating the capsaicin. Chien teaches encapsulation of active agent in microreservoirs comprising amphiphilic solvent. Therefore, the combination of Chien and Holt will provide capsaicin in microreservoirs comprising amphiphilic solvent.

> Applicant argues that capsaicin is mentioned in Embil's reference as an optional ingredient and not as an active agent. The amphiphilic solvent systems mentioned in Embil (1,3 butylene glycol, dipropylene glycol and DGME) are for the purpose of enhancing the delivery of nimesulide; and not capsaicin. Embil does not teach or suggest that the amphiphilic solvent systems are to be incorporated into the microreservoirs of the applicants' claimed invention.

In response to this argument, applicant's attention is directed to the scope of the present claims that is drawn to product, an all the elements of the product are disclosed by the combined teachings of the references. The future intended use of the individual

ingredients does not impart patentability to claims directed to product. Amphiphilic solvents are expected to interact the same way when combined with capsaicin since compounds and their properties are inseparable. It is further argued that in considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972). In the present case, even if capsaicin was disclosed by Embil as optional ingredient, and even amphiphilic solvent was disclosed to enhance the delivery of other drugs, capsaicin was preferred optional ingredient and was suitable to combine with amphiphilic solvent as evident by example 3 at col.4 of the reference. The teaching of Embil would have suggested to one having ordinary skill in the art to deliver capsaicin in the microreservoirs produced by the combination of Chien and Holt that are made of the amphiphilic solvent since Embil disclosed suitability of combining capsaicin and amphiphilic solvent.

> Applicant argues that Holt and Embil are non-analogous to the applicants' invention or that of Chien in that Holt is directed to lotion and Embil is directed toward the composition being in the form of a gel, solution, ointment or spray and not toward a topical patch which comprises a self-adhesive amine resistant polysiloxane matrix wherein the matrix contains liquid microreservoir.

In response to this argument, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Holt is pertinent to the problem with which applicant is concerned which topical delivery of irritant capsaicin to the skin. Holt is further in the field of applicant's endeavor which is topical and transdermal drug delivery. Regarding Embil, the reference is in the field of applicant's endeavor which is topical and transdermal drug delivery.

> Applicant argues that Schacht is directed toward a means for improving transdermal delivery of rotigotine and does not teach or suggest the use of capsaicin in their microreservoirs. Schacht also does not teach the use of amphiphilic solvents with capsaicin in the microreservoirs which is part of the applicant's invention. In addition, neither Holt, Embil or Schacht address Chien's omission for the teaching the use of an amine resistant polysiloxane or for teaching the requisite concentration of capsaicin in the microreservoir droplets.

In response to this argument, it is argued that Schacht is relied upon for the solely teaching of suitability of mixture of high tack polysiloxane with medium tack polysiloxane in transdermal delivery of the drugs. Chien suggested silicone adhesive, and the specified amine resistant silicone adhesive mixture is taught by Schacht. Chien further suggested the concentration of the drug as set forth in this office action. Schacht teaches the advantage of using mixture of high tack polysiloxane (BIO-PSA 4301) and

medium tack polysiloxane (BIO-PSA 4201) for transdermal delivery matrix which is providing optimum balance between good adhesion and little cold flux.

> Applicant argues that as the determination of obviousness requires consideration of the references as a whole, it is unclear why one of ordinary skill in the art would selectively ignore all of the remaining elements from the Chien, Holt, Embil and Schacht references not cited in the Office Action especially when the skilled artisan would not have the applicants' claims as a blueprint to arrive at the applicants' claimed invention.

In response to this argument, it is argued that the invention as a whole with all the claimed limitation are taught by the combination of the cited prior art. The prior art is relied upon for all it suggest to one having ordinary skill in the art. It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.,* 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." In addition, "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit. But it need not seek out precise teachings directed to the challenged claim's

specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ". Pp. 11-14. KSR INTERNATIONAL CO. v. TELEFLEXINC. ET AL. (2007). It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).
In response to the argument that it is unclear why one of ordinary skill in the art would selectively ignore all of the remaining elements from the references, it is argued that omission of an element and its function is obvious if the function of the element is not desired. *Ex parte Wu* , 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989). See also *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965); and *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon using applicants' claims as a blueprint to arrive at the applicants' claimed invention, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

9. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US '983, US '501, US '671, and US '206 and further in view of US 7,247,315 ('315).

The combined teachings of US '983, US '501, US '671, and US '206 are previously discussed as set forth in section 6 of this office action.

Although the combined teachings of US '983, US '501, US '671, and US '206 teach mixture of polysiloxane adhesive polymers, however, does not teach silicone oil in the adhesive composition.

US '315 teaches transdermal delivery patch comprising drug matrix layer comprising polydimethylsiloxane and dimethicone (silicone oil) in an amount of 4-7% that acts as plasticizer for the polydimethylsiloxane and such an amount has as drug flux rate lowering effect providing more predictable and uniform flux rate of the drug through the skin (abstract; col.3, lines 21-25, 32-33, 39-45).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal device comprising polysiloxane matrix containing microreservoirs comprising capsaicin in an amphiphilic solvent as disclosed by the combined teachings of US '983, US '501, US '671, and US '206, and further add 4-7% silicone oil to the polysiloxane matrix as disclosed by US '315 because US '315

teaches that 4-7% dimethicone when added to polysiloxane acts as plasticizer for the polysiloxane and has drug flux rate lowering effect providing more predictable and uniform flux rate of the drug through the skin, with reasonable expectation of having transdermal device comprising polysiloxane matrix containing microreservoirs comprising a capsaicin in an amphiphilic solvent and further comprising 4-7% silicone oil wherein the flux rate of capsaicin delivery through the skin is predictable and uniform.

Response to Arguments

10. Applicant's arguments filed 11/04/2008 have been fully considered but they are not persuasive.

> Applicant hereby repeats the arguments regarding the combination of Chien, Holt, Embil and Schacht. Applicant further argues that Brown (US '315) does not remedy the deficiencies of the combination of Chien, Holt, Embil and Schacht and is not even appropriate for its intended use to support the rejection of claim 12; Brown only serves to add to the number of possible number of solutions and further weakens any assertion of obviousness. There is no reason why one of ordinary skill in the art would be directed toward silicone oil in Brown to the exclusion of all other possible teachings within the Brown reference. Brown is directed toward the delivery of the active ingredient from a solid drug reservoir which differs from the microdispersions of Chien and encapsulating agents of Holt. There would be no expectation of success that taking an individual element from Brown would not change the function of either Chien, Holt, Embil and Schacht's invention alone or in combination.

In response to this argument, the examiner hereby repeats the argument regarding the combination of Chien, Holt, Embil and Schacht as set forth in this office action. Additionally, it is argued that Brown is relied upon for the solely teaching of the addition of silicone oil to silicone adhesive for the advantage of providing more uniform flux of the drug through the skin. The cited references show that it was well known in the art at the time of the invention to use the claimed ingredients in compositions in transdermal drug delivery. It is well known that it is prima facie obvious to combine two

or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA1972); *In re Susi*, 58 CCPA 1074, 1079-80) 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

It has been held that “When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious.” *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.,* 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious,” the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” In addition, "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ". Pp. 11-14. KSR INTERNATIONAL CO. v. TELEFLEXINC. ET AL. (2007). It is well established that the

claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

11. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US ‘983, US '501, US ‘671, and US ‘206, and further in view of US 5,494,680 ('680).

The combined teachings of US ‘983, US '501, US ‘671, and US ‘206 are previously discussed as set forth in section 6 of this office action.

Although the combined teachings of US ‘983, US '501, US ‘671, and US ‘206 teach backing material, however, does not teach the specific backing materials as claimed by claim 16.

US ‘680 teaches transdermal delivery device having backing that is flexible such that the device conforms to the skin. The material of the backing can be polyester or ethylene vinyl acetate copolymer (col.4, line 60 till col.5, line 1).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal device comprising polyester backing layer and polysiloxane matrix containing microreservoirs comprising capsaicin in an amphiphilic solvent as disclosed by the combined teachings of US ‘983, US '501, US ‘671, and US ‘206, and replace the polyester backing material with ethylene vinyl

acetate copolymer as disclosed by US ‘680, because US ‘680 teaches backing made of such material is flexible such that the device conforms to the skin, with reasonable expectation of having transdermal device comprising backing layer of ethylene vinyl acetate copolymer and matrix of polysiloxane containing microreservoirs comprising a capsaicin in an amphiphilic solvent wherein the device is flexible and conforms to the skin, therefore comfortable to the user.

Response to Arguments

12. Applicant's arguments filed 11/04/2008 have been fully considered but they are not persuasive.

> Applicant hereby repeats the argument with regard to the combination of Chien, Holt, Embil and Schacht. Additionally, applicant argues that Peterson (US ‘680) used for specific elements different from the above cited references and there is no reason to pick specific elements from Peterson to the exclusion of their other teachings.

In response to this argument, the examiner hereby repeats the argument regarding the combination of Chien, Holt, Embil and Schacht as set forth in this office action. Additionally, it is argued that Peterson is relied upon for the solely teaching of the materials of the backing layer that are the same as claimed by applicant. Peterson further teaches the advantage of these backing materials as being flexible such that the device conforms to the skin.

13. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US ‘983, US '501, US ‘671, and US ‘206, and further in view of US 6,239,180 ('180).

The combined teachings of US ‘983, US '501, US ‘671, and US ‘206 are previously discussed as set forth in section 6 of this office action.

Although the combined teachings US ‘983, US '501, US ‘671, and US ‘206 teach analgesic effect of capsaicin, and further teaches treating neuralgia, however, the combination of the references does not explicitly teach capsaicin treats of neuropathic pain as claimed by claim 17.

US ‘180 teaches that capsaicin and its analog are extremely effective therapy for treating neuropathic pain (abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal device comprising layer and polysiloxane matrix containing microreservoirs comprising capsaicin in an amphiphilic solvent as disclosed by the combined teachings of US ‘983, US '501, US ‘671, and US ‘206, and use the patch to treat neuropathic pain as disclosed by US ‘180, because US ‘180 disclosed that capsaicin and its analog are extremely effective therapy for treating neuropathic pain, with reasonable expectation of having transdermal device comprising polysiloxane layer containing microreservoirs comprising a capsaicin in an amphiphilic solvent that treat neuropathic pain effectively.

Response to Arguments

14. Applicant's arguments filed 11/04/2008 have been fully considered but they are not persuasive.

> Applicant hereby repeats the argument with regard to the combination of Chien, Holt, Embil and Schacht. Additionally, applicant argues that Robbins (US ‘180) does not teach the topical patch of applicant’s invention.

In response to this argument, the examiner hereby repeats the argument regarding the combination of Chien, Holt, Embil and Schacht as set forth in this office action. Additionally, it is argued that Robbins is relied upon for the solely teaching and confirmation that capsaicin is useful to treat neuropathic pain.

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 7,063,860 teaches that capsaicin is a lipophilic drug used to treat neuropathic pain, and can be administered transdermally (col.5, lines 15-20, 34-43; col.22, line 25).

Conclusion

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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